PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/666,168
Filing Date:	September 19, 2003
Applicant:	Phillip Martin Gibbs et al.
Group Art Unit:	3738
Examiner:	Bruce E. Snow
Title:	MODULAR PROSTHETIC HEAD HAVING A FLAT PORTION TO BE IMPLANTED INTO A CONSTRAINED LINER
Attorney Docket:	5490-000301

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We hereby declare under penalty of perjury as follows:

1. We are the inventors of the claimed subject matter of the subject patent application.

2. Exhibit A is a page from an engineering notebook that is dated and witnessed, with dates redacted, prior to January 3, 2002.

3. Before January 3, 2002, we conceived of and/or reduced to practice in the United States, a prosthesis system for implantation into an anatomy that includes a ball portion and a cup portion with an entrance. The ball portion has a portion with a dimension equal to or less than a dimension of the entrance to the cup portion. The ball

portion also has a portion with a dimension greater than a dimension of a concave area, as evidence by the following.

4 The page in Exhibit A is entitled "Constrained Liner Idea" that illustrates, in the upper left-hand corner thereof, a liner with a ring that would interact with the liner and it is stated in Exhibit A a "liner that fits ordinary shells with ring that is installed at Biomet".

5. The page in Exhibit A also states that "the endo type head would have a small flat around the equator to allow it to go into the liner. The flat could be positioned in a way that the head would be unlikely to dislocate, but in a position that would allow a surgeon to position the leg to reduce the hip in surgery". This concept is further illustrated in the lower right-hand corner of the page as an exemplary head illustrated with a flat portion thereon.

6. Exhibit B is a R&D Work Request, with date information redacted that is evidence that parts were made by us or on our orders and delivered to us on or before January 3, 2002.

7. Exhibit B includes drawing prints showing configurations and dimensions of various head portions for a femoral head replacement that includes a reduced radius or "flat" portion.

8. Exhibit C is an "Investigational" router, with date information redacted, that illustrates a design of a liner that can include a ring positioned near an opening into an interior portion of the liner. Exhibit C includes a redacted start date before January 3, 2002 (on the first page) and a completion date of January 3, 2002 (shown as the date of "Inspect" on the last page of the "Investigation").

9. The liner illustrated in Exhibit C would allow, and was made for, insertion of a head portion, as illustrated in Exhibit B, to enter the interior portion of the liner when an axis of a the reduced radius area is aligned with an axis of the entrance.

10. Exhibit D is an Applied Technology Mechanical Test Request Form and accompanying drawings and test data, with proprietary data redacted. Exhibit D includes a Requested by W. J. Slone and a Date Submitted of January 3, 2002 and a Test Close-Out Information that illustrates that the requested tests were Conducted by K. Howard and Dated Completed was January 7, 2002.

11. Exhibit D includes a cover sheet that describes that two sets of liners, one with a Cobalt reinforcement ring and one with a titanium reinforcement ring were used with three different types of femoral heads in a lever-out test. The three heads were a 36mm full spherical, a 36mm full spherical with a 34.5 mm circumferential flat, and a 36mm full spherical with a 35.0 mm circumferential flat.

13. Exhibit D also illustrates that the various samples, Sample 4, Sample 5, Sample 12, Sample 13, Sample 6, Sample 7, Sample 14, and Sample 15, that clearly include the circumferential flats in a starting position and in a maximum load position relative to a liner that includes a constraining ring.

14. Exhibit A, with dates redacted illustrates a conception and/or reduction to practice of the subject matter of the claims in the subject application. Exhibits B and C provide evidence that the subject matter of the claims in the present application was reduced to practice and built on or before January 3, 2002. Finally, Exhibit D is evidence that parts embodying the subject matter of the claims of the present invention were tested on or before January 7, 2002

15. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 3-28-06

Phillip Martin Gibbs

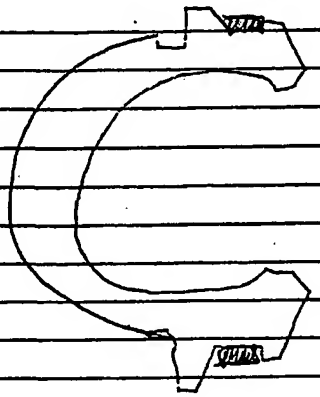
Dated: 3-28-2006

William Jason Slone

PROJECT NAME _____ NOTEBOOK NO. _____

[redacted]

CONSTRAINED LINER IDEA



LINER THAT FITS ORDINARY SHELLS WITH RING THAT IS INSTALLED AT BIOMET

(NO SLITS)

LIKE JASON SLONE'S IDEA. ~~SHRINK THE LINER BY~~

MIGHT EVEN BE ABLE TO SHRINK POLY IN COLD ENVIRONMENT / WARM RING TO ~~INSTALL~~ ASSEMBLE

AND/OR

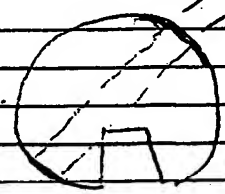
SURGEON INSTALLS THIS LINER IN CUP

WOULD HAVE LARGE ENOUGH I.D. TO OFFER GOOD RANGE OF MOTION WITH TYPE ONE TAPER.

OFFER VARIOUS NECK LENGTH ENDO TYPE HEADS TO MATE WITH ID OF LINER

THE REALLY UNIQUE THING HERE IS THAT THE ENDO TYPE HEAD WOULD HAVE A SMALL FLAT AROUND THE EQUATOR TO ALLOW IT TO GO INTO THE LINER. THE FLAT COULD BE POSITIONED IN A WAY THAT THE HEAD WOULD BE UNLIKELY TO DISLOCATE, ~~IN OTHER WORDS IT WOULD BE IMPOSSIBLE TO~~, BUT IN A POSITION THAT WOULD ALLOW THE SURGEON TO POSITION THE LEG TO REDUCE THE HIP IN SURGERY

NOT FULL SPHERE AS MUCH AS POSSIBLE NO FLAT (YES) (NO)



FLAT WITH RADIUSES ON BOTH SIDES TO MINIMIZE INCREASED WEAR

SIGNATURE [redacted] DATE [redacted] 20__

READ AND UNDERSTOOD William V. Slone DATE [redacted] 20__

BIOMET INC R&D WORK REQUEST

Request Date: [redacted]

Engineer: Phil Gibbs ext. 1690
Project Number: Product Name: modular heads with flats

Make Per:
☒ Print (Attached)
☐ CAD Data File

18399l.tif 18399b.tif 18399c.tif
18399d.tif 18399e.tif 18399f.tif
18399g.tif 18399h.tif 18399i.tif
18399j.tif 18399k.tif 18399a.tif

Using:
☒ Material On Hand
☐ Material Provided
☐ Parts Provided

Qty: 6

Bill To:
☐ Distributor
☒ Departmental Charge

Price Quoted

Time and Materials:

Instructions:

this research was originated to support constrnined liner development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log

Date	Hr's	Name	Notes From Shop
[redacted]	6.00	Monty Lackey	
[redacted]	10.00	Don DeCook	
[redacted]	8.00	Monty Lackey	
[redacted]	8.00	Monty Lackey	

Traceable Material

Material	Lot #	Locatio

Vendor No:

Engineering Information

P.O. No:

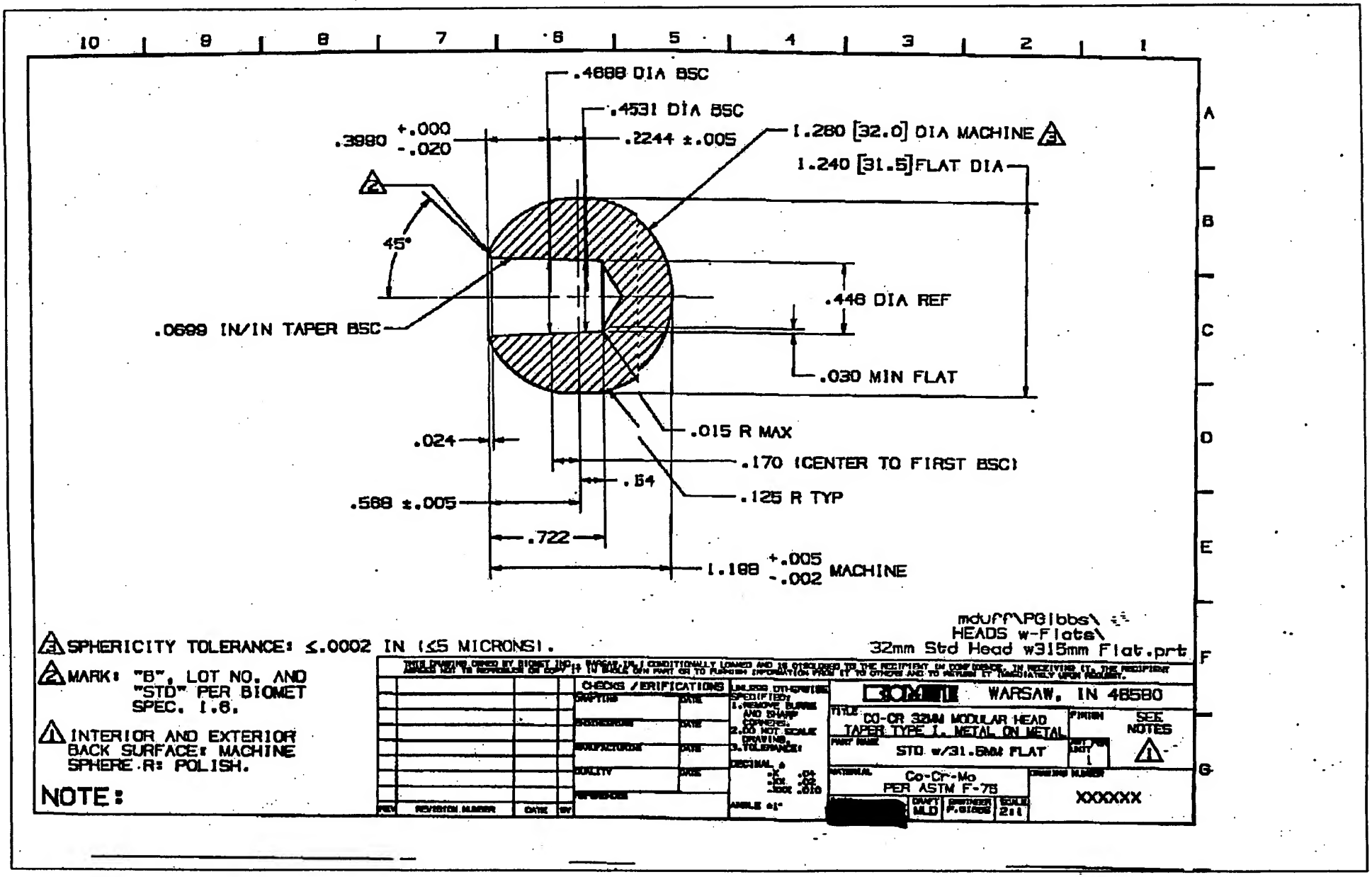
Req, No:

Comp. Date: [redacted]

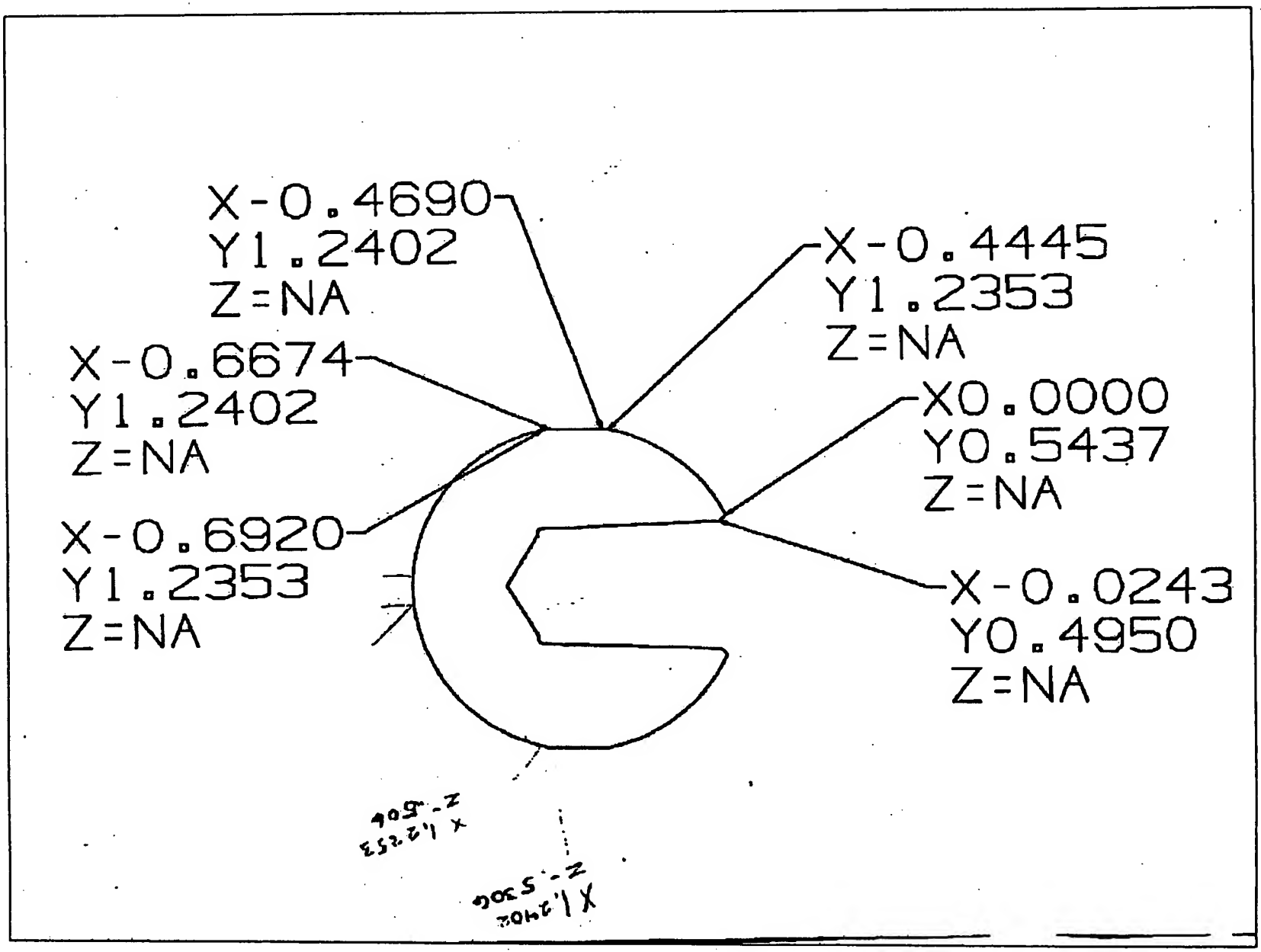
Completed Documents:

Department:	Hips	Other:
Classification:	R&D	
Total Hours:	32.00	
Order No.: 18399		

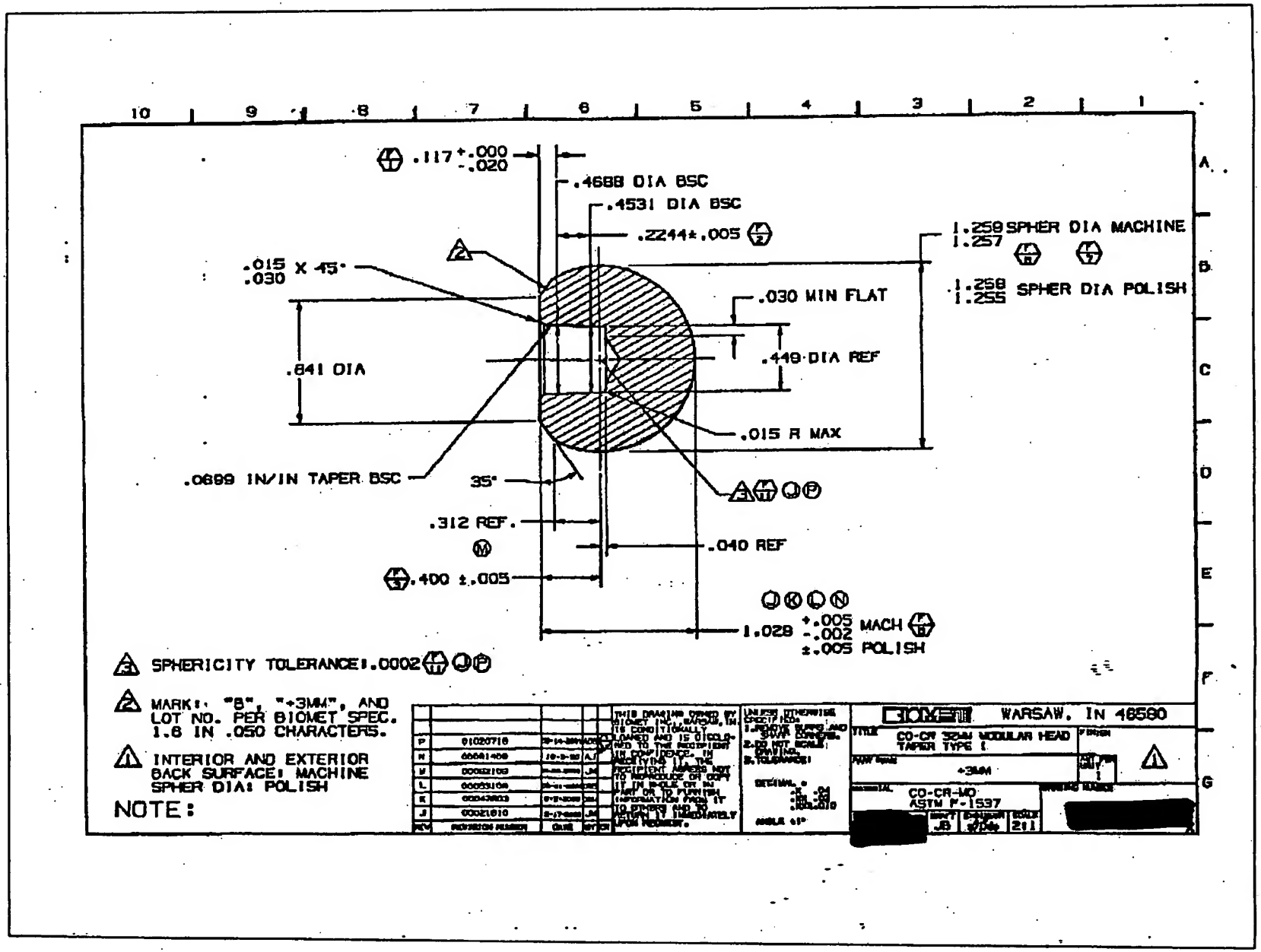
Printed with UGS JT2Go 5.1



Printed with UGS JT2Go 5.1



Printed with UGS JT2Go 5.1



PAGE: 19 TIME: 21:11 DATE: [redacted]

C A R L Z E I S S Measurement system

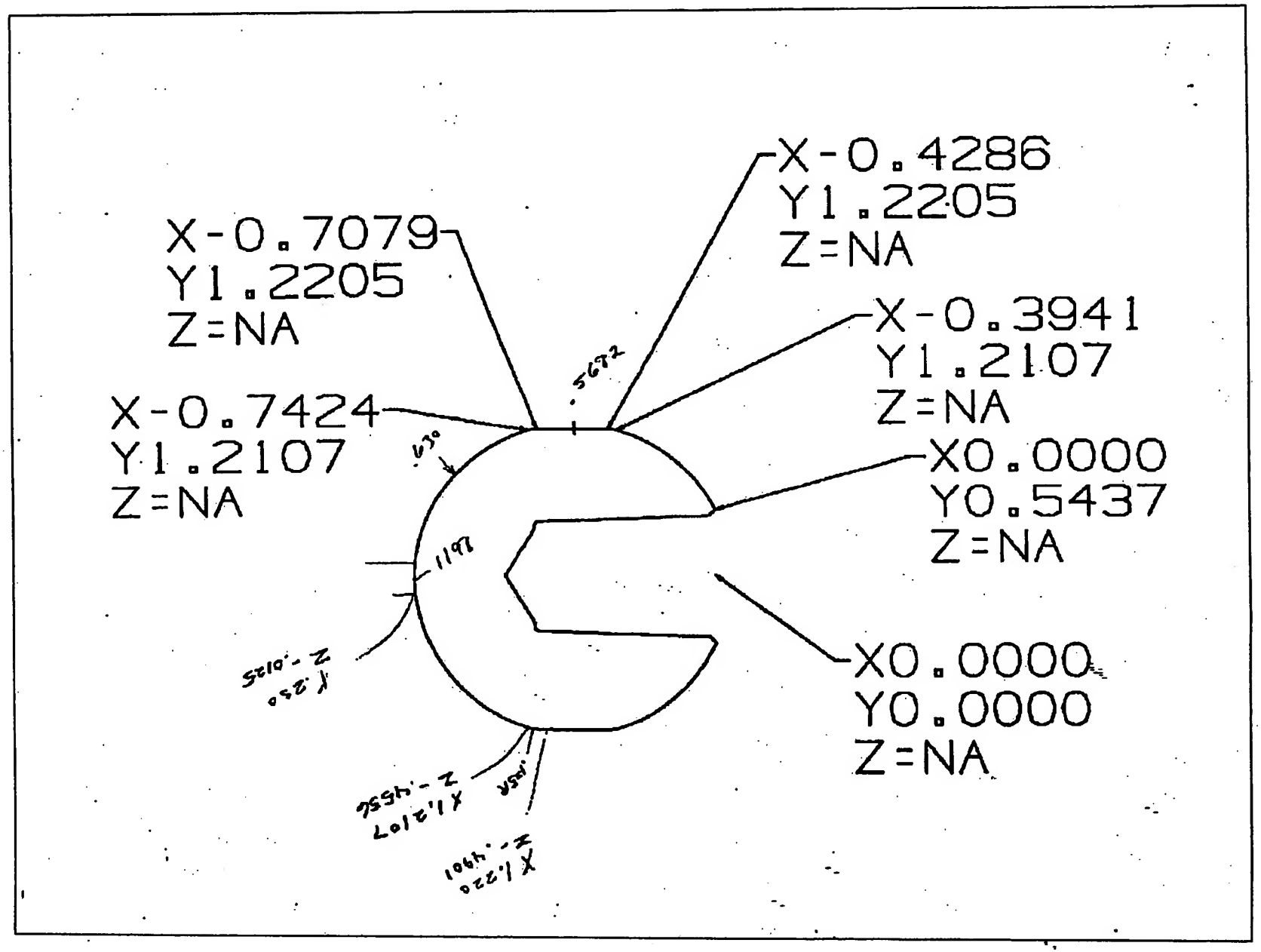
No.	TASK	REM	BY	ACTUAL	NOMINAL	UPPERTOL	LOWERTOL	DEVIATION	OVER
7	VALUE EQUALS SPHERE EQUATION								
1	SPHERE		Z	.59884					
			R	.71302					
			MD	.00173					

PAGE: <3 TIME: 0:14 DATE: [redacted]

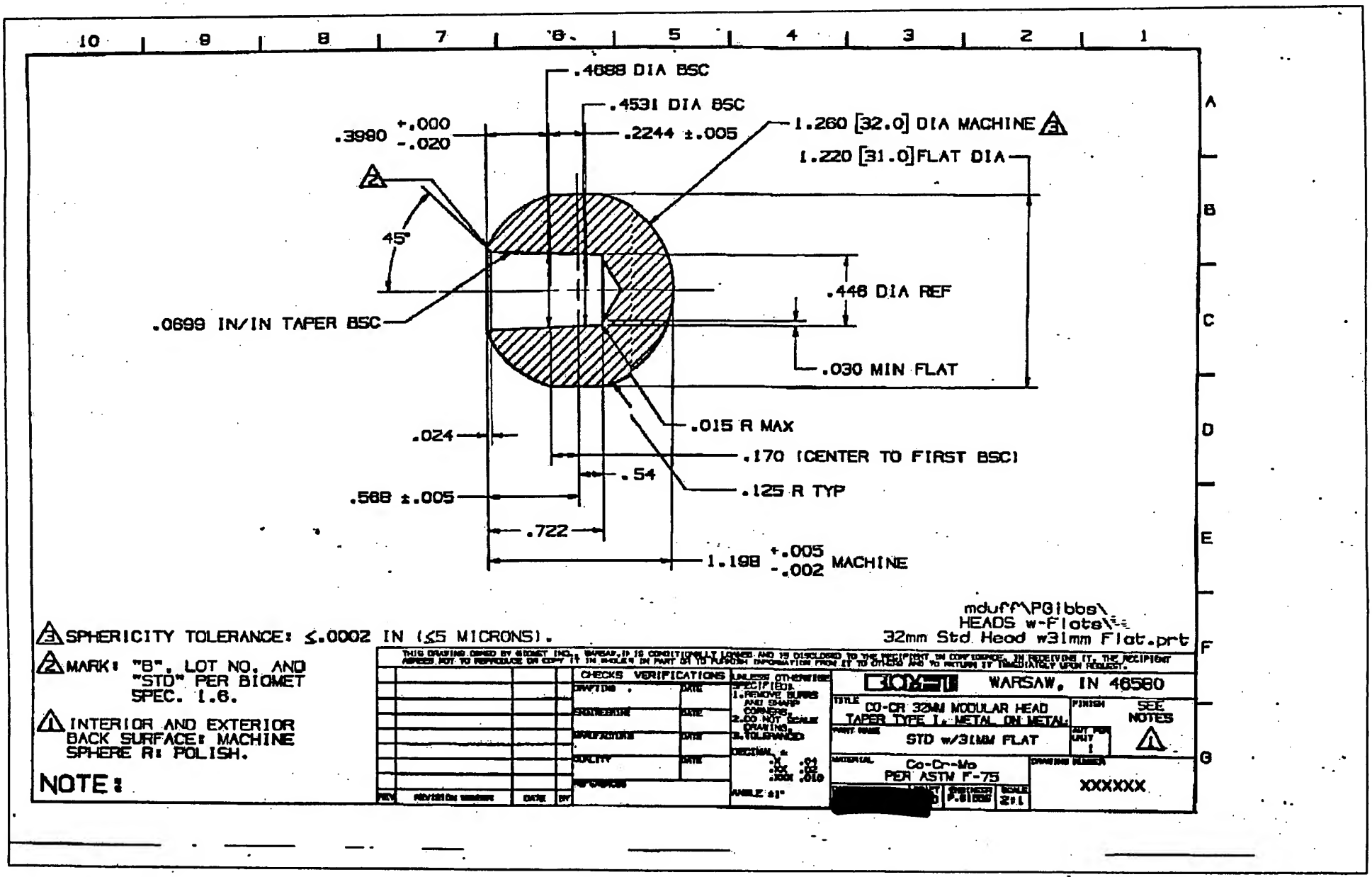
C A R L Z E I S S Measurement system

No.	TASK	KEM	SY	ACTUAL	NUMINAL	UPPERTOL	LOWERTOL	DEVIATION	OVER
Z VALUE EQUALS SPHERE LOCATION									
1	SPHERE		Z	.60395					
			R	.71041					
			No	.00029					

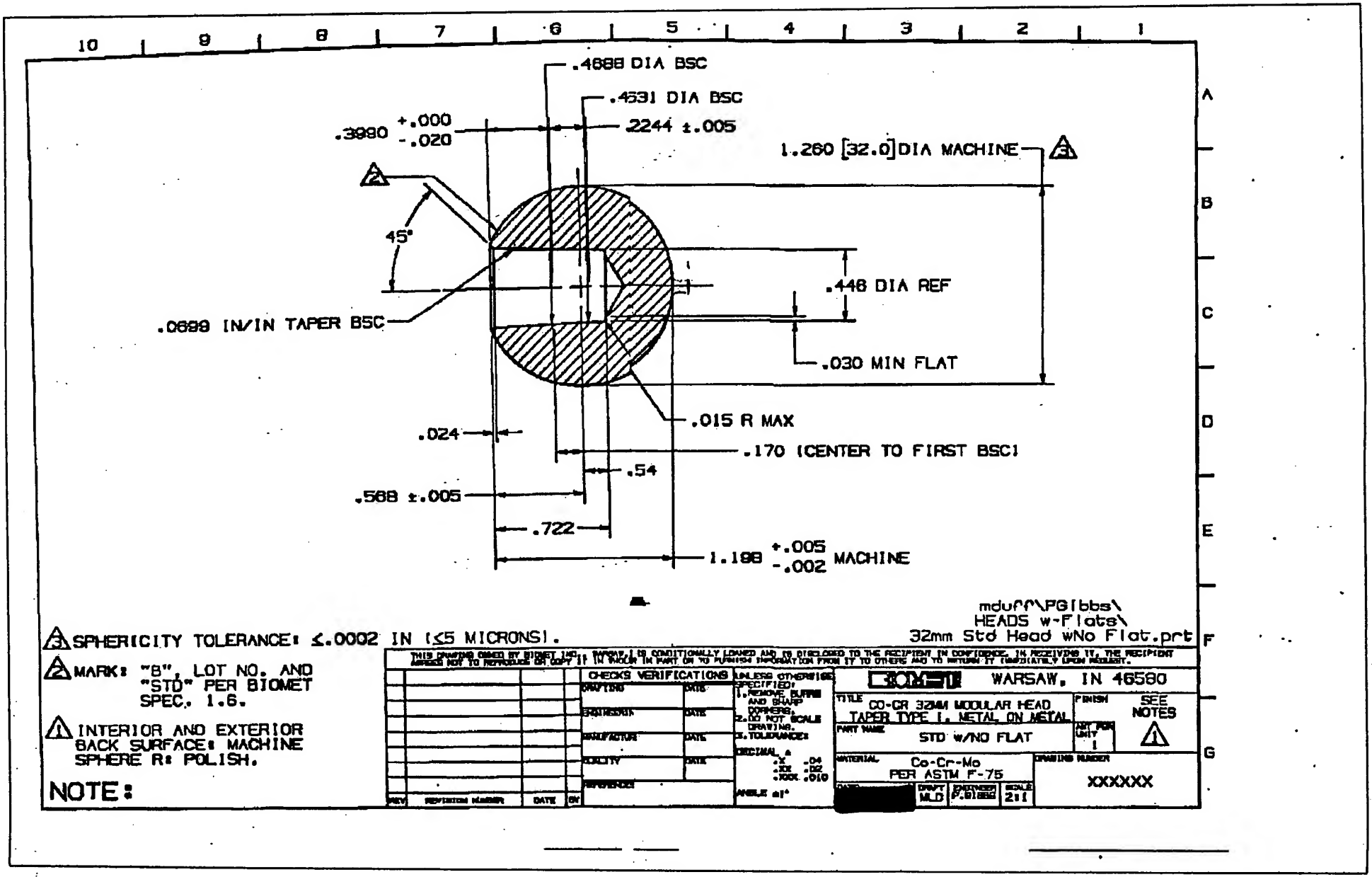
Printed with UGS JT2Go 5.1



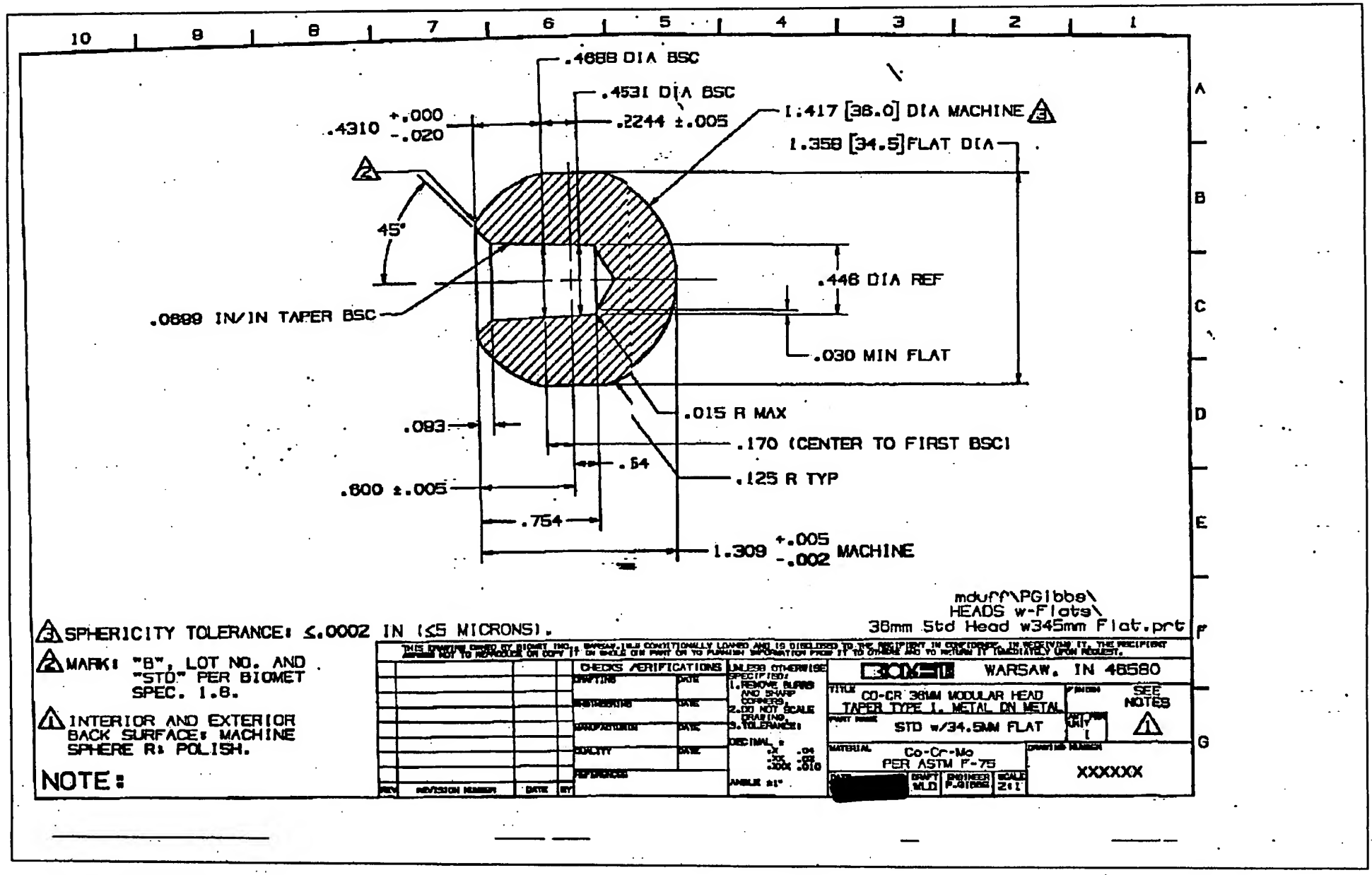
Printed with UGS JT2Go 5.1



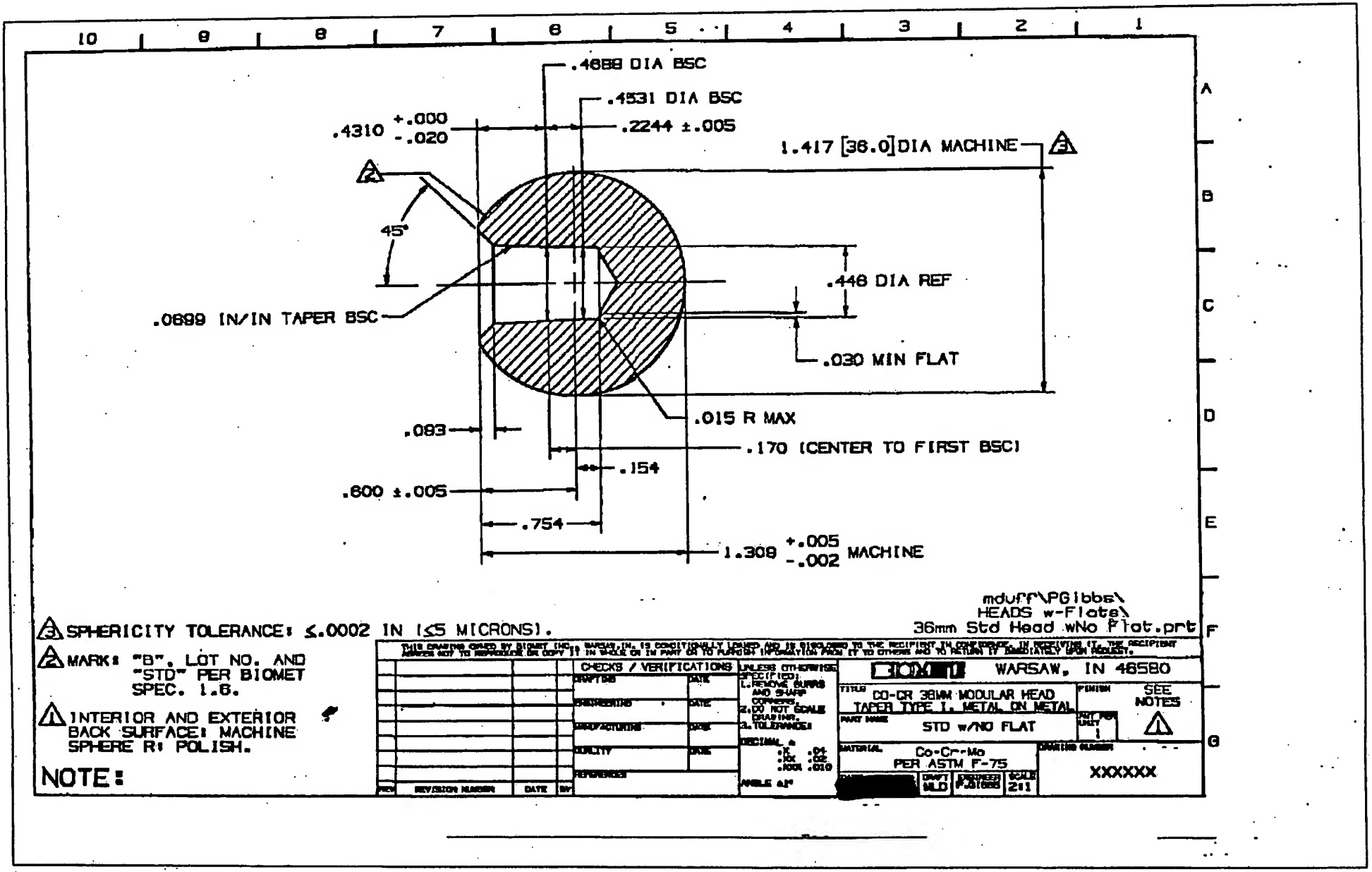
Printed with UGS JT2Go 5.1



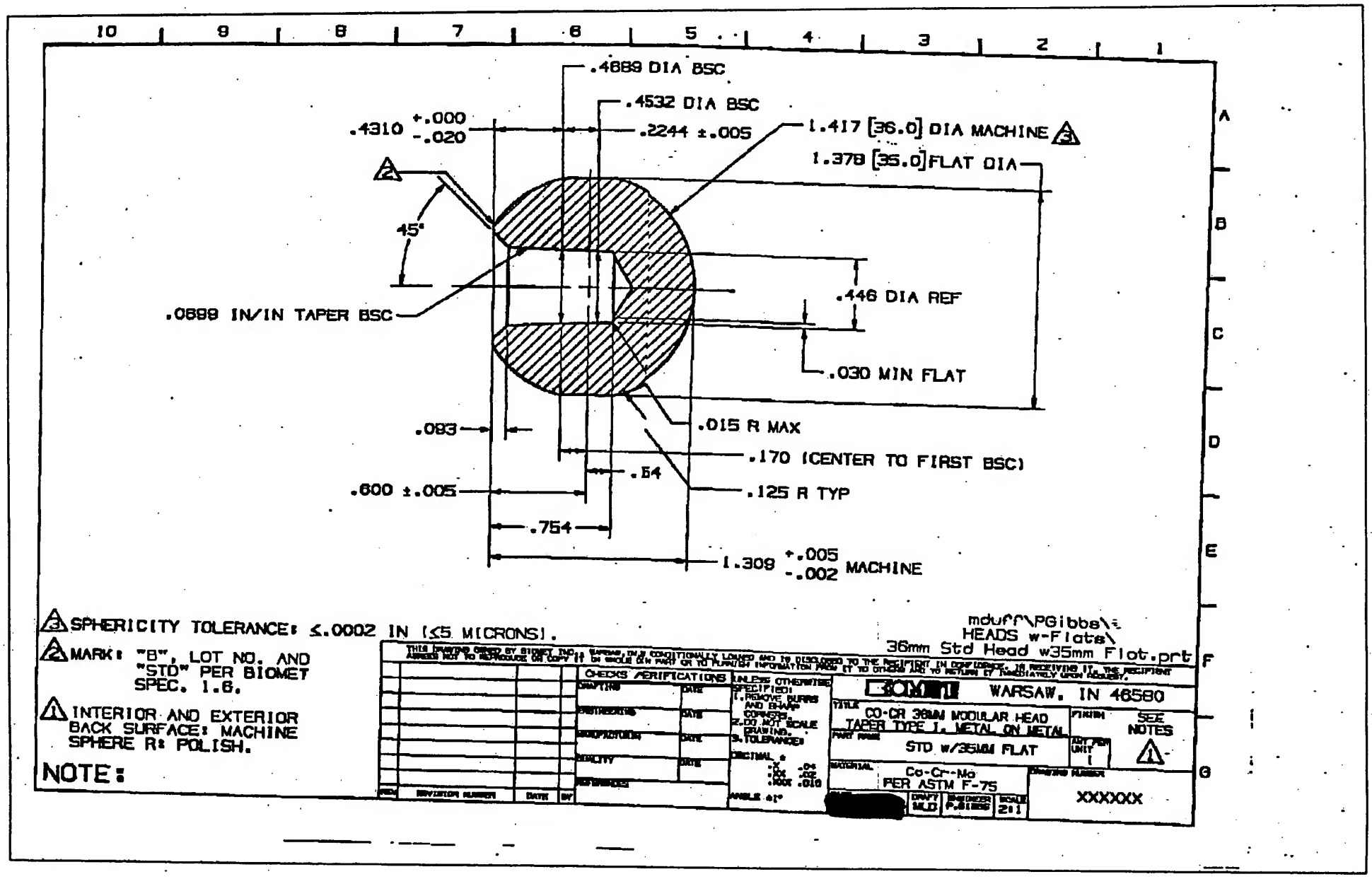
Printed with UGS JT2Go 5.1



Printed with UGS JT2Go 5.1



Printed with UGS JT2Go 5.1



BIOMET R&D WORK REQUEST

Request Date: [redacted]

Engineer: Phil Gibbs ext. 1690
Project Number: Product Name: modular heads with flats

Make Pen
- ☒ Print (Attached)
- ☐ CAD Data File

Using: Qty: 6
- ☒ Material On Hand
- ☐ Material Provided
- ☐ Parts Provided

Bill To: ☐ Distributor ☒ Departmental Charge
Price Quoted

Needs ASAP

Time and Materials:

Instructions:

this research was originated to support constrained liner development. by decreasing ROM slightly, we should be able to experience much greater pull-out and lever-out and still be able to assemble. question is increased wear concerns

Shop Log			
Date	Hr's	Name	Notes From Shop
[redacted]	6	Monty	
	10	D.Lok	
	8	Monty	
	8	Monty	

Traceable Materials		
Material	Lot#	Location
01-02-0014A	090932	the Cage

Vendor No:
P.O. No:

Req. No:
Comp. Date: Complete

Completed Documents:

Engineering Information		
Department:	Hips	Other:
Classification:		
Total Hours:	0.00	
Order No.: 18399		

ENTERED

ENTRY USER ID: CRG # TIMES PRINTED: [redacted] MM

M815390 STOCK LOCATION: NEW1 CURRENT DATE: [redacted] PAGE: 1

FINISHED ITEM	DESCRIPTION	START DTE	JOB NO.	ORDER QTY	PLNR
	INVESTIGATIONAL CONST.TRI-POLAR	0/00/00	0000000	20.000	88

ATTACH SAMPLE LABEL HERE:

M815390

INVESTIGATIONAL

REF INVESTIGATIONAL LOT 815390

INVESTIGATIONAL

RETURN TO GREG PORTER

LOT 815390 QTY. 1

BIOMET ORTHOPEDICS, INC.
[redacted]

STERILE
2002-01

DRAWING LIST: REV. SIZE PLOT

NO PRINT REQ. A Y PLOTS AVAILABLE FOR ALL PRINTS !

COMPONENT ITEM	DESCRIPTION	U/M	TYPE	QTY.	REQD OPER
01-07-0422	755840 2.000 IN RD ARCOM UHMWPE	IN	2	~~95.00~~ 40'12	

728010 6292 12/10 +64

755880 6292 12/11

728000 6292 12/18 +27

728000 6292 12/19 27

788970 6292 12/20 +13½

05093438

+13½

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
10408	0020	CUT BLANK			

.TN6120981

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
[redacted]	6292	20	1						

ENTRY USER ID: CRG # TIMES PRINTED: MM

M815390 STOCK LOCATION: NEW1 CURRENT DATE: [redacted] PAGE: 2

FINISHED ITEM DESCRIPTION START DTE [redacted] JOB NO. ORDER QTY PLNR

INVESTIGATIONAL CONST.TRI-POLAR 0/00/00 0000000 20.000 88

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
28010	0040	TRUN O.D. LB1694	5.00			

.TN6120999

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	INSPECT S/L	CLOCK NUMBER	REWORK PIECES
[redacted]	5477	40	20	—	—	—	—	—	—

28000	0060	MILL SCALLOPS VR0207	5.00						

.TN6121005

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	INSPECT S/L	CLOCK NUMBER	REWORK PIECES
[redacted]	5252	0060	20	0	—	—	—	—	—

28010	0080	BORE I.D. LB4603	5.00						

.TN6121013

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	INSPECT S/L	CLOCK NUMBER	REWORK PIECES
[redacted]	5477	80	11	—	—	—	—	—	—
	5477	80	9	—	—	—	—	—	—

ENTRY USER ID: CRG # TIMES PRINTED: [redacted] MM

M815390 STOCK LOCATION: NEW1 CURRENT DATE: [redacted] PAGE: 3

FINISHED ITEM	DESCRIPTION	START DTE	JOB NO.	ORDER QTY	PLNR
INVESTIGATIONAL CONST.TRI-POLAR		0/00/00	0000000	20.000	88

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
10834	0100	TRIM COMPLETE	10.00			

Return to Gregg Porter Ext. 1852

.TN6121021

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
[redacted]	6043	100	20						

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
11715	0120	POLY LASER ETCH	38.61			

.TN6121039

1 ETCH "SAMPLE" ON O.D. RADIUS

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
1-3	4805	120	20						

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
10914	0140	CLEAN POLY	33.33			

See Tammy Rhoades FSL 1-3-02

.TN6121047

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
1/9/02	3337	140	16	4 FSL					

ENTRY

M815390

FINISHED

TIMES PRINTED: MM

CURRENT DATE: [redacted] PAGE: 1

START DT[illegible] JOB NO. ORDER QTY PLNR

0/00/00 0000000 20.000 88

"RUSH"

SHIP STERILE fcl. 1-4-03

TION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
	50.00			

.TN6121054

TV Timmy) DO PART! TSL 1-3-03

DATE	AP CES	ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
1-3	0					

12116 0180 PACKAGE STERILE 33.33

.TN6121062

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
1-3	4496	180	16						

12118 0200 LABEL & BOX 30.03 LOGO

See Timmy Process TSL 1-3-03

.TN6121070

1 RETURN TO GREGG PORTER EXT 1852

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	ACC	INSPECT REJ	S/L	CLOCK NUMBER	REWORK PIECES
1/3/02	4789	200	16						

ENTRY USER ID: CRG # TIMES PRINTED: [redacted] MM

M815390 STOCK LOCATION: NEW1 CURRENT DATE: [redacted] PAGE: 5

FINISHED ITEM	DESCRIPTION	START DTE	JOB NO.	ORDER QTY	PLNR
INVESTIGATIONAL CONST.TRI-POLAR		0/00/00	0000000	20.000	88

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
00005	0220	INSPECT	83.33			

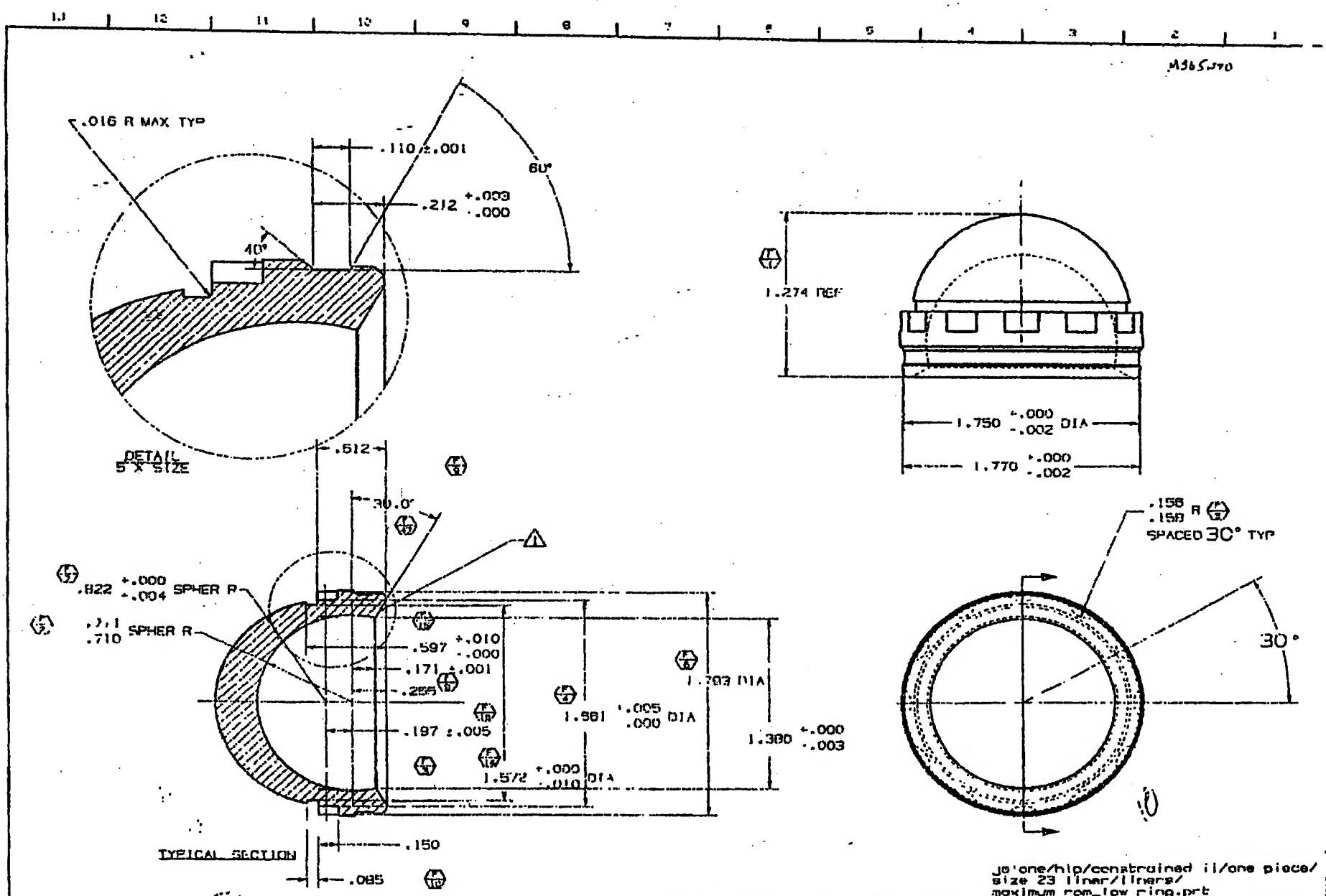
.TN6121088

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	INSPECT S/L	CLOCK NUMBER	REWORK PIECES
F3	6688	220	16	0	16	0	16		

WORK CENTER	OP. SEQ.	OPERATION DESCRIPTION	PCS. PER HOUR	TOOL NUMBER	PROCESS NUMBER	LABEL COLOR
09000	0240	STERILIZE				

.TN6121096

DATE	CLOCK NUMBER	OPER. NUMBER	PIECES PROD.	SCRAP PIECES	INSPECT ACC	INSPECT REJ	INSPECT S/L	CLOCK NUMBER	REWORK PIECES
		240	16	0					



⚠ MARK: "B", LOT NO., AND "PROTOTYPE" (SIZE), PER BIOMET SPEC. 1.61.
EXAMPLE: B XXXXXX "PROTOTYPE"

NOTE:

je'one/hip/constrained il/one piece/size 23 liner/liners/maximum rom_low ring.prt

CHECKS / VERIFICATIONS

WARSAW, IN 46580

RING-LOC TRI-POLAR CONSTRAINED LINER

SIZE 23

MACHINE

ARCOM UHMWPE

INVESTIGATIONAL

[redacted]

Applied Technology Mechanical Test Request Form

Project : Constrained Liner II Project #: HP000180

Title: Lever-out with 3 different 36mm Co-Cr Modular Heads

Test Type: _ Fatigue X Static _ Rotating Beam _ Wear
_ Other (specify) _____

Conducted: X In-House
_ Outside Lab (specify) _____

Test Components: (Part A is primary component for test)

	Part Name	Part #	Lot #	Size	Qty
A	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
B	23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
C	36mm Fully-spherical Modular Head	Investigational		36mm	1
D	36/34.5mm Fully-spherical Modular Head with 34.5mm circumfrencial flat	Investigational		36mm	1
E	36/35.0mm Fully-spherical Modular Head with 35.0mm flat	Investigational		36mm	1

If the test components are not finished production parts, please state why.

Material:

A	B	C	D	E	
	X				Ti-6Al-4V
.X		XXX			CoCr
					P85/15
					P82/18

A	B	C	D	E	
					Stainless Steel (type)_____
X	X				UHMWPE
					LactoSorb
					Other (specify)_____
					Ceramic (specify)_____

Processing: (Check all that apply for each test component)

A	B	C	D	E	
X	X	X			Wrought
					Molded
					Welded
					Shot Peened Intensity
					Ion Implanted
					TiN Coated
					Chem Etched
					Finished Goods (Lot#)
					Wire EDM'D

A	B	C	D	E	
					Forged
X	X	X	X	X	Machined
					Heat Treated (specify)
					Blasted (#_____)
X	X				Ceramic Bead Blast
		X	X	X	Laser Etched
X	X				Sterilized (gamma)
X	X	X	X	X	Cleaned (powerwash/alchol)
		X	X	X	Honed

A	B	C	D	E	
					Cast
X		X	X	X	Passivated
X	X				Packaged
					HA Coated
					Full Plasma Spray
					MacroBond P Spray
					Plasma Nitrided
					Other ____
		X	X	X	Polished

Specify differences between multiple specimens: The only difference between the two liners is the constraining ring. The liners themselves are from the same lot.

Objective(s) of Test: Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

Test Procedure # See atached page (Outline the desired procedure if not a standard procedure).

Test Specifications: _____

Deviations from Standard: _____

_____

_____

Data to be Collected:
- x Load vs. Deflection
- x Max. Load
- __ Weight Loss
- __ # of Cycles to Failure
- x Max. Deflection
- __ Other _____

Special Intructions: _____

_____

_____

Requestor to be present when test is started? X Yes __No

Requested By: W. F. Stone Date Submitted: 1/3/2002

Test Close-Out Information:

Conducted By: K. Howard Date Completed: 1-7-2002

Lab Book Reference: S-24 pg. 23

Test Specimen Disposition: X Archived __Returned To Engineer __Discarded

Requestor Comments:

_____

_____

_____

_____

_____

Requestor: W. F. Stone Date: 1/14/2002

Lab Supervisor: Date:

Biomet Mechanical Test Lab
Static Test Data Sheet

Test #MT2439 Date Test Started 1-7-2002 Requestor J. SLONE

Title CONSTRAINED LINER II; LEVER OUT Machine ID RAYMOND

Actuator Rate .008"/SEC. = .48"/MIN.

Sketch of Test Set-Up: (note all relevant distances and angles)

Specimen#	Max. Load	DATA FILE:	Specimen#	Max. Load	DATA FILE:
Sz. 36/34½ FLAT HEAD			Sz. 36 FULL HEAD		
#4.	41.6 lbs.	2439-1.TXT	#8.	40.5	2439-9.TXT
#5.	43.2	2439-2.TXT	#16.	41.0	2439-10.TXT
#12.	46.6	2439-3.TXT			
#13.	46.4	2439-4.TXT			
Sz. 36/35 FLAT HEAD					
#6	43.5	2439-5.TXT			
#7	44.5	2439-6.TXT			
#14	49.3	2439-7.TXT			
#15.	46.0	2439-8.TXT			

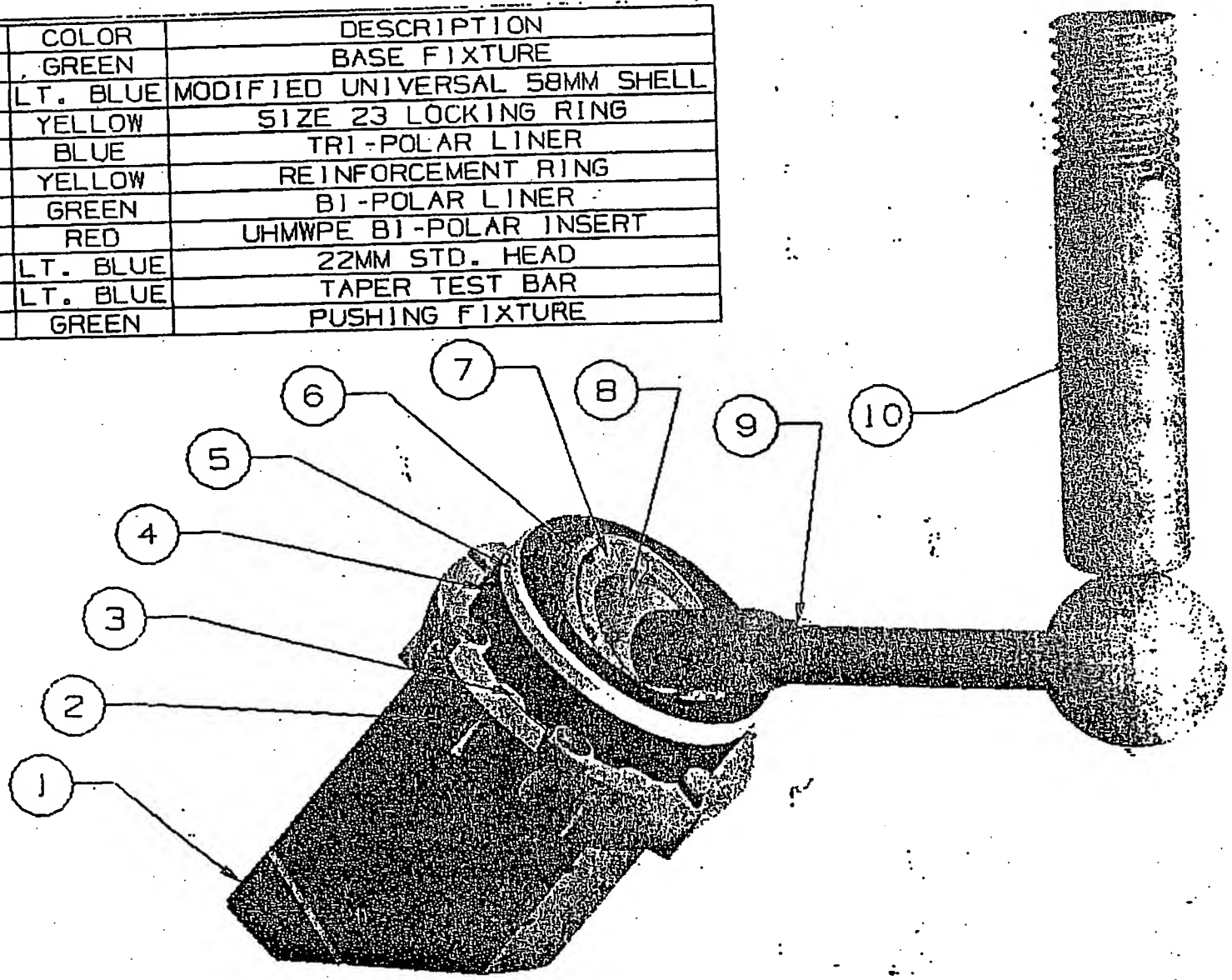
Average: Average:

Notes:

Date Test Completed: 1-7-2002 Conducted by: K. HOWARD

Book# S-24 Continued on Page Page 23

OBJECT NO.	COLOR	DESCRIPTION
1	GREEN	BASE FIXTURE
2	LT. BLUE	MODIFIED UNIVERSAL 58MM SHELL
3	YELLOW	SIZE 23 LOCKING RING
4	BLUE	TRI-POLAR LINER
5	YELLOW	REINFORCEMENT RING
6	GREEN	BI-POLAR LINER
7	RED	UHMWPE BI-POLAR INSERT
8	LT. BLUE	22MM STD. HEAD
9	LT. BLUE	TAPER TEST BAR
10	GREEN	PUSHING FIXTURE



TOP WORK

HEAD Sz. 36/34½ FLAT LEVER-OUT

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

2439-1 41.6 lbs

#1

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34½ FLAT LEVER-OUT

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

2439-2 43.2 lbs.

#5.

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34½ FLAT

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER-OUT

2439-3 46~~6~~ lbs.

#12

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/34½

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER OUT

2439-4 46.4 lbs.

#13.

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER OUT

2439-5 43.5 lbs.

#6.

LOT 815390
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

~~HEAD Sz 36/35 FLA~~
LEVER OUT.

#7. 2439-6 44.5.

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz 36/35 FLAT

BIOMET ORTHOPEDICS, INC.
ST BELL DRIVE
BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

#14. 2439-7 49.3 lbs.

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/35 FLAT

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER-OUT

#15. 2439-8 45.99 lbs.

LOT 815390
AFFIX TO PATIENT RECORDS

* FIRST RUN CAME OUT OF SHELL

HEAD Sz. 36/36

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER-OUT

#8. 2439-9 40.5 lbs.

LOT 815390
AFFIX TO PATIENT RECORDS

HEAD Sz. 36/36

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. INVESTIGATIONAL
INVESTIGATIONAL
RETURN TO GREG PORTER

LEVER-OUT

#16. 2439-10 41.0 lbs.

LOT 815390
AFFIX TO PATIENT RECORDS

Test Report MT-2439
Lever-Out with 3 different 36mm Co-Cr Modular Heads

Test Site:

Biomet Inc.
Airport Industrial Park
Warsaw, IN 46580

Conducted By:

Jason Slone — Development Engineer
Kelly Howard — Laboratory Technician/Supervisor

Jason Slone 12/11/2002

Dates Conducted:

January 7, 2002

Objective:

Determine the amount of torque required to lever-out three different 36.0 mm modular head designs from the liner, as well as determining how much if any a Cobalt Reinforcement ring will strengthen design from a Titanium Reinforcement Ring.

Materials:

Part Name	Part Number	Lot Number	Size	Quantity
23 Constrained +5 Liner w/Cobalt Ring	Investigational	815390	23	6
23 Constrained +5 Liner w/Ti-6Al-4V Ring	Investigational	815390.	23	6
CoCr Reinforcement Ring	Investigational	R&D	23	6
Ti-6Al-4V Reinforcement Ring	Investigational	R&D	23	6
36mm Full Sphere Modular Head	Investigational	R&D	36	1
36mm/35 flat Full Sphere Modular Head	Investigational	R&D	36/35	1
36mm/34.5 flat Full Sphere Modular Head	Investigational	R&D	36/34.5	1

The 23 Constrained Liners were manufactured complete at Biomet Warsaw. The Retaining Rings and Modular Head were manufactured at Biomet Warsaw in the Research and Development area. The rings were manufactured complete except for chemical etch, sterilization and packaging processes, which have no effect of this test.

Methods:

See Attached Sheet for Test Procedure

Calculations:

Lever-Arm:

The calculated lever-arm for this test was done using the CAD system. See Attached Figures with Sample Numbers. The constrained liner design was taken and rotated until the lever-out bar was horizontal. Then the head was constrained so that it must pop out of the liner perpendicular to the face of that liner. The maximum displacement was then used to determine where the Force from the actuator was being placed.

Percent Increase of CoCr Reinforcement Ring:

[(Average Torque Ti-6Al-4V)-(Average Torque CoCr)]/(Average Torque Ti-6Al-4V)

Results:

The results of the lever out test were as follows.

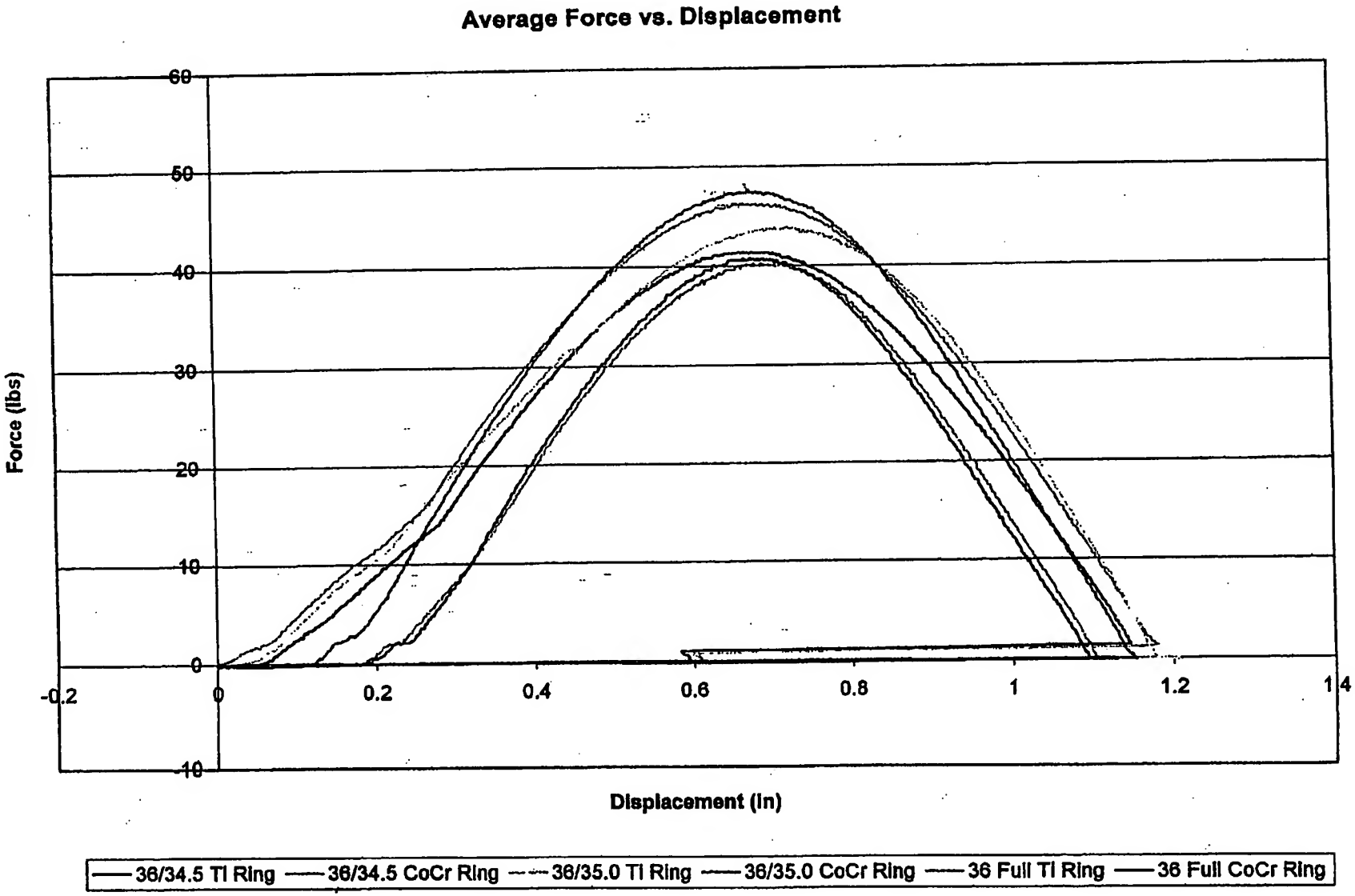
Mechanical Test 2439					
Specimen #	Maximum Displacement (in)	Maximum Recorded Force (lbs)	Calculated Lever Arm (in)	Calculated Torque (in-lbs)	Modular Head Size
4	0.652	41.6	3.216	133.8	36/34.5
5	0.662	43.2	3.215	138.9	
12A	0.686	46.3	3.215	148.9	
13	0.710	45.7	3.209	146.6	
6	0.687	43.5	3.213	**139.8**	36/35.0
7	0.746	44.5	3.206	**142.7**	
11	0.690	49.0	3.213	157.4	
15	0.680	46.0	3.215	147.8	
8	0.720	40.5	3.209	130.0	36/36
16	0.693	41.1	3.210	131.9	

Note: Blocks in Gray are Liners with a Cobalt Chrome Reinforcement Ring;
Bold Numbers are maximum Torque

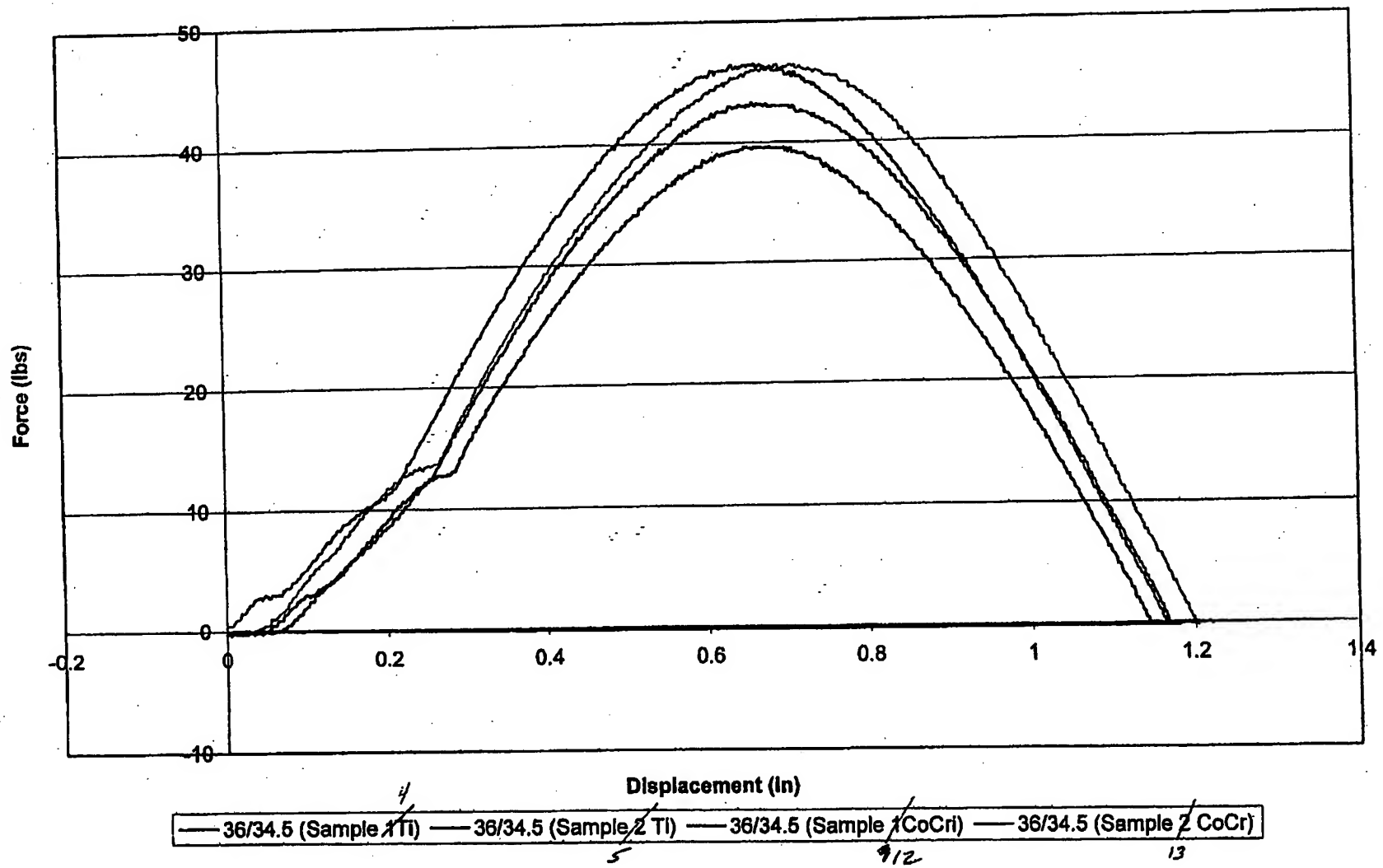
Conclusion:

As can be seen from the data the maximum amount of torque is acquired using a CoCr Reinforcement Ring with a 36/35.0 modular head. This scenario makes sense because it will displace a small amount of polyethylene when placed into the liner, but maintain the most amount of surface area when in a lever-out position. See tests reports MT2239 and MT2412 showing what the difference can be when using a full spherical head compared to a head that is not a complete sphere.

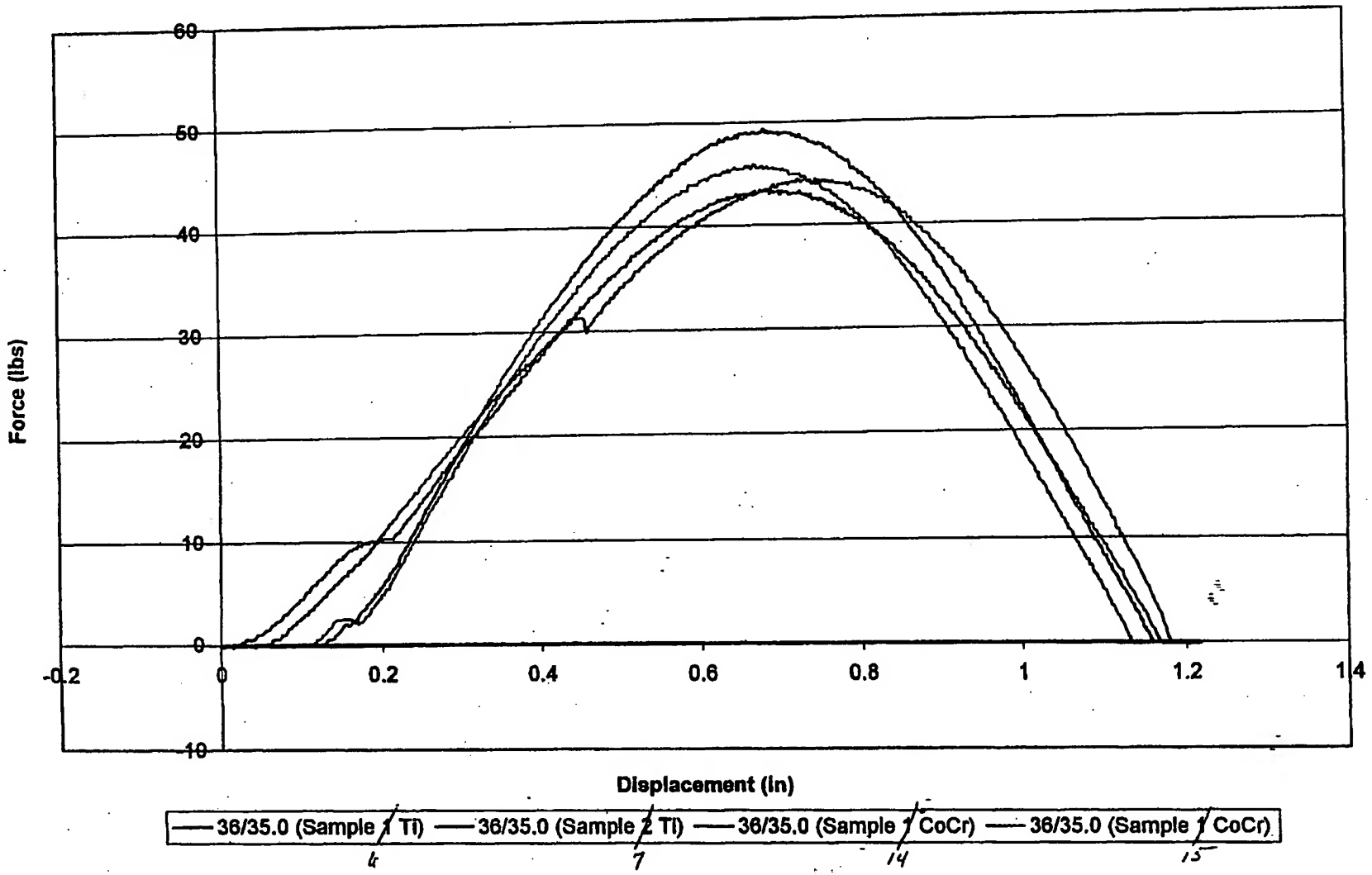
The 36/35.0 modular head shows the best results with either the CoCr or Ti-6Al-4V Reinforcement Rings. The CoCr Reinforcement Ring increases the leverout strength of this UHMWPE constrained liner design by roughly 9%.


Average Force vs. Displacement
Force (lbs)
60
50
40
30
20
10
0
-10
-0.2
0
0.2
0.4
0.6
0.8
1
1.2
1.4
Displacement (in)
36/34.5 Ti Ring
36/34.5 CoCr Ring
36/35.0 Ti Ring
36/35.0 CoCr Ring
36 Full Ti Ring
36 Full CoCr Ring

Force vs. Displacement

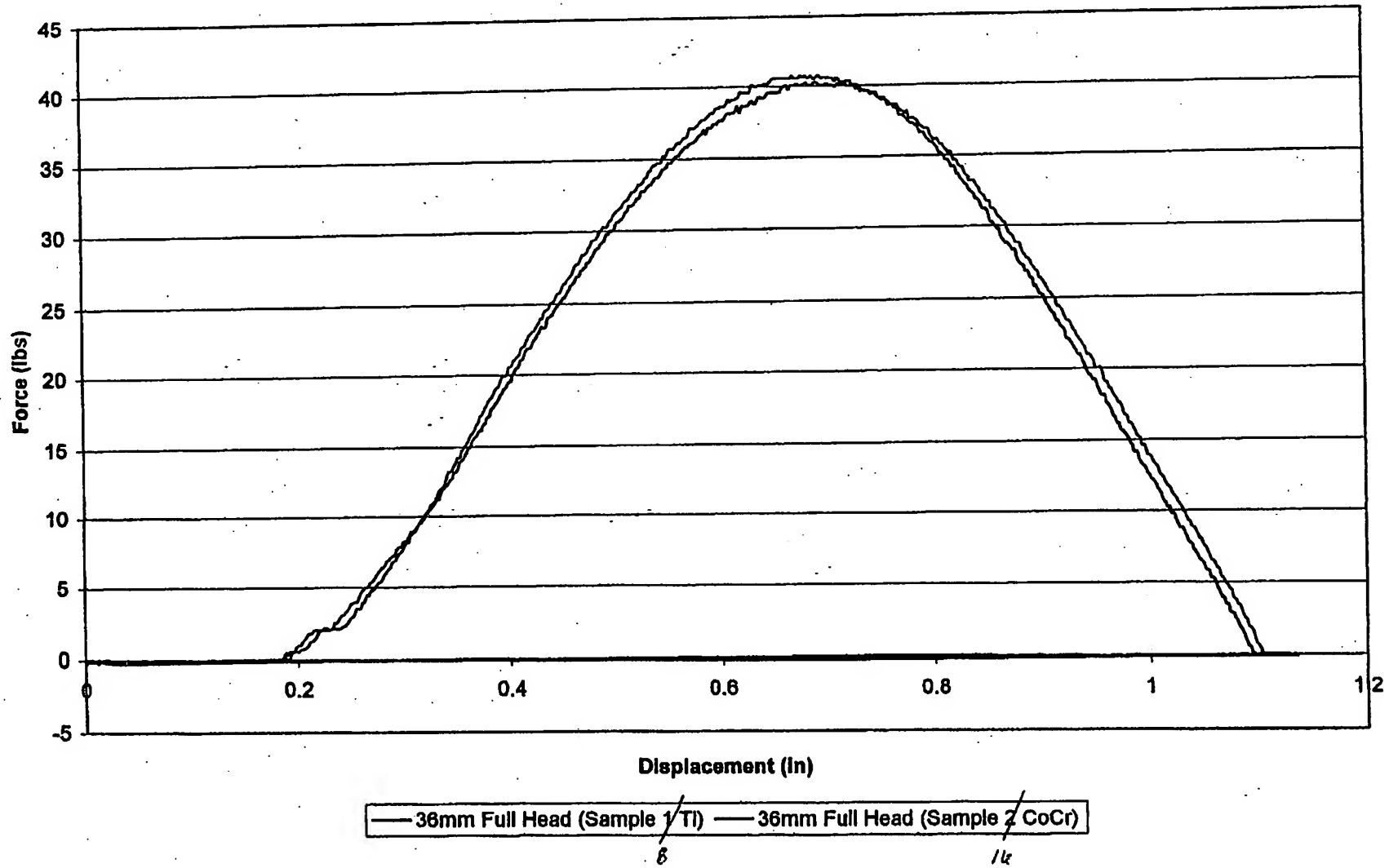


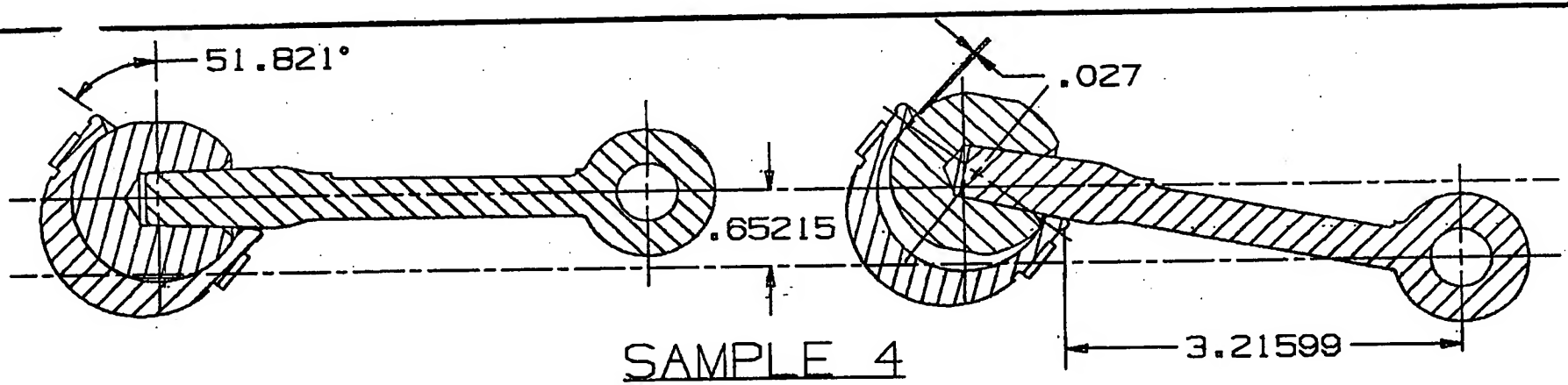
Force vs. Displacement



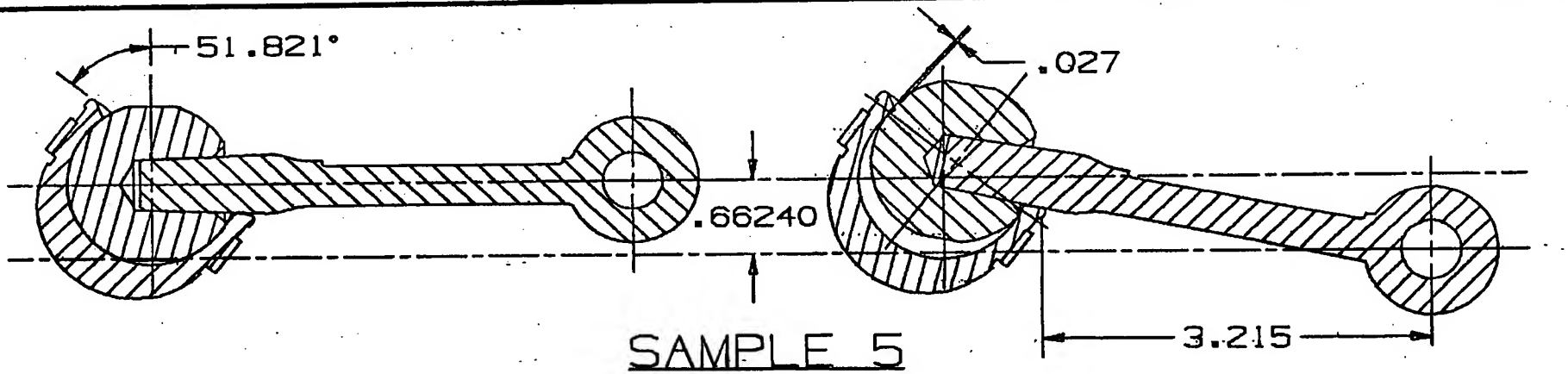
4 7 14 15

Force vs. Displacement

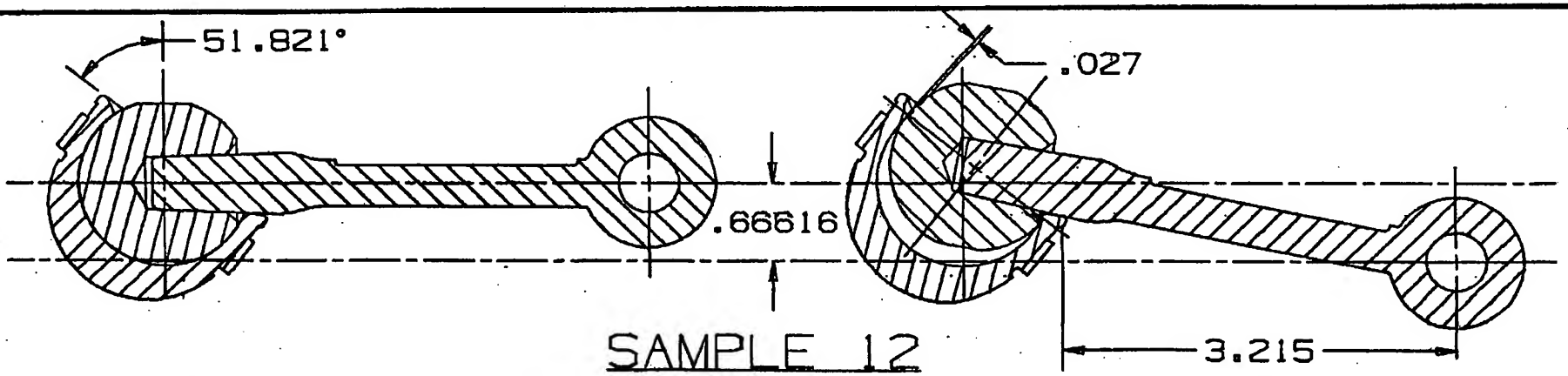




SAMPLE 4



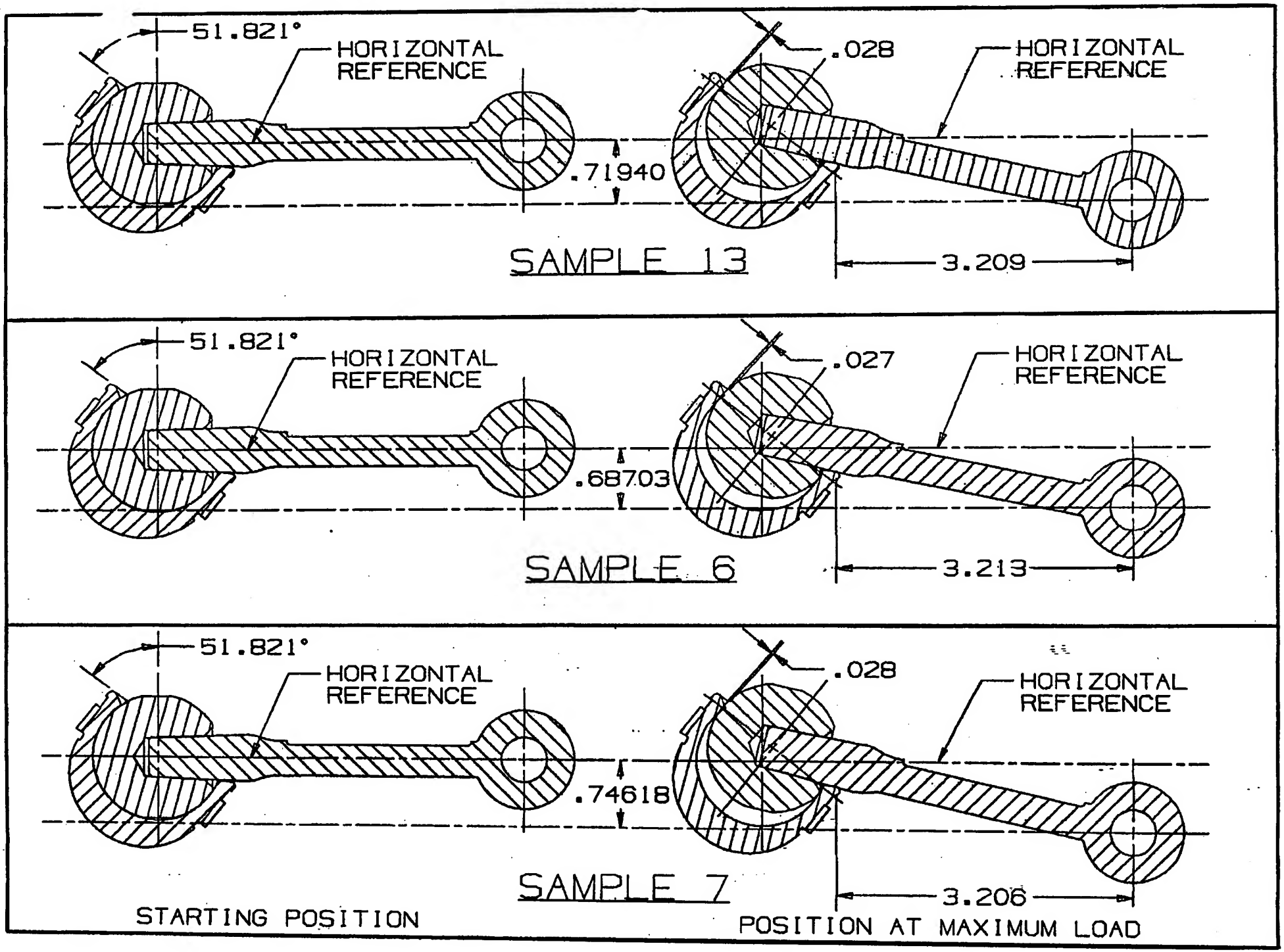
SAMPLE 5

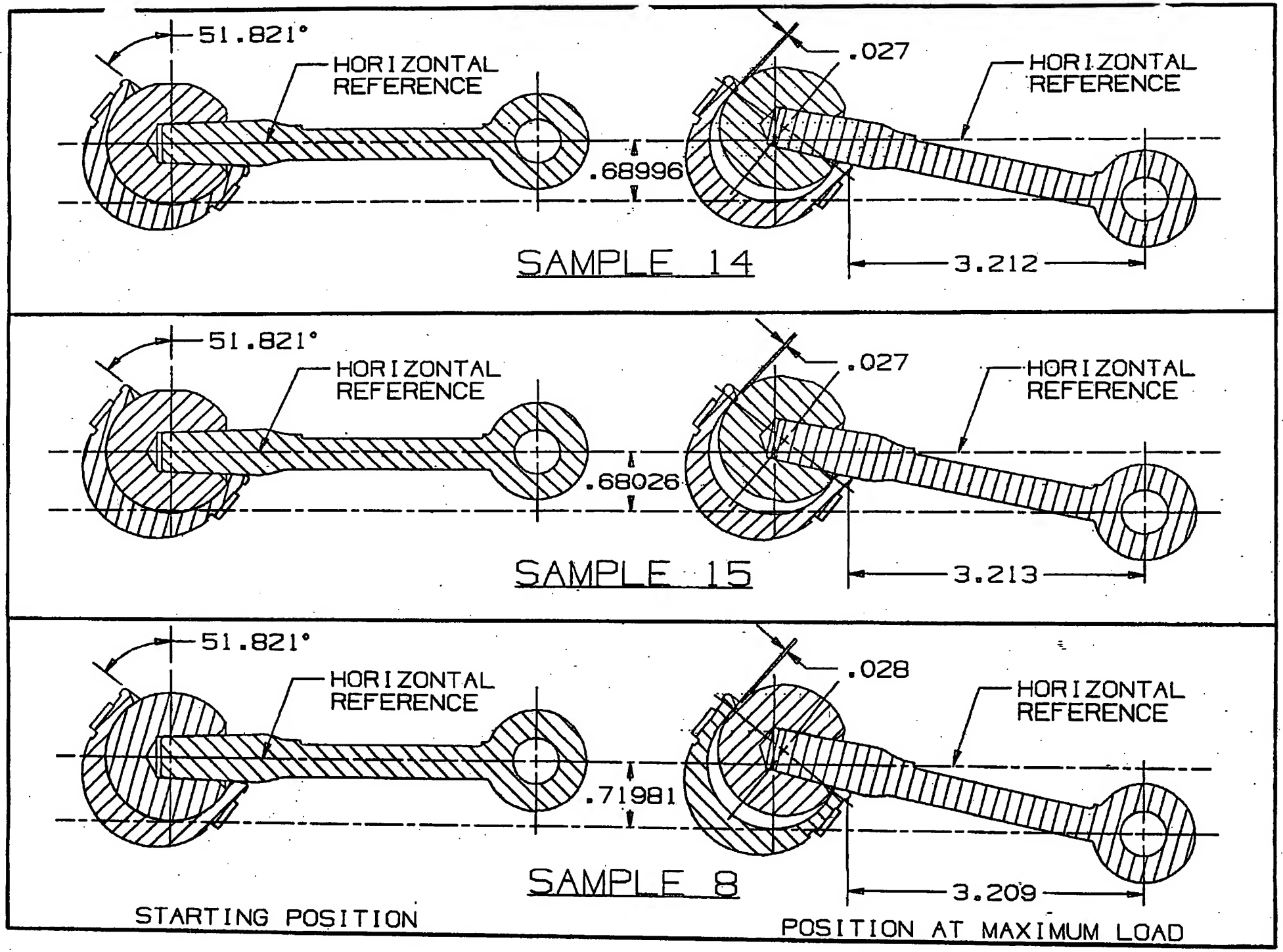


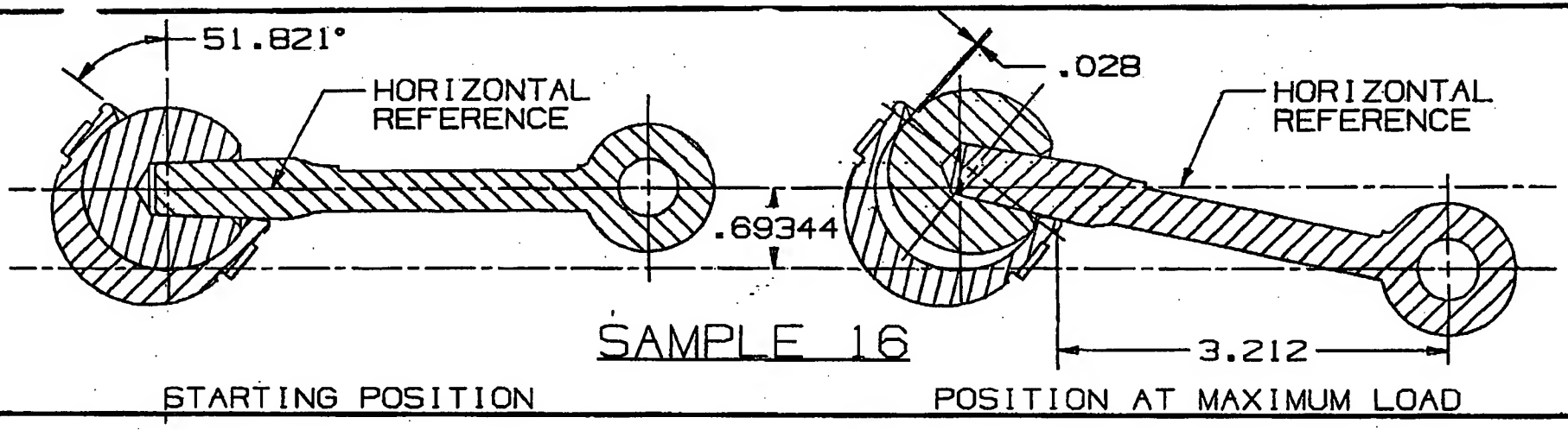
SAMPLE 12

STARTING POSITION

POSITION AT MAXIMUM LOAD


51.821°
HORIZONTAL REFERENCE
.71940
.028
HORIZONTAL REFERENCE
3.209
SAMPLE 13
51.821°
HORIZONTAL REFERENCE
.68703
.027
HORIZONTAL REFERENCE
3.213
SAMPLE 6
51.821°
HORIZONTAL REFERENCE
.74618
.028
HORIZONTAL REFERENCE
3.206
SAMPLE 7
STARTING POSITION
POSITION AT MAXIMUM LOAD


51.821°
HORIZONTAL REFERENCE
.027
HORIZONTAL REFERENCE
.68996
3.212
SAMPLE 14
51.821°
HORIZONTAL REFERENCE
.027
HORIZONTAL REFERENCE
.68026
3.213
SAMPLE 15
51.821°
HORIZONTAL REFERENCE
.028
HORIZONTAL REFERENCE
.71981
3.209
SAMPLE 8
STARTING POSITION
POSITION AT MAXIMUM LOAD



SAMPLE 16

STARTING POSITION

POSITION AT MAXIMUM LOAD

36mm Constrained Liners

Specimen #	Initial I.D Dimension	I.D after Liq.N	Initial O.D Dimension	O.D after Liq.N	Initial O.D Ring Groove	O.D Ring Groove after Liq.N	Ring I.D	Ring Material
1	0.71722	0.71807	0.83100	0.83123	1.5770	1.5775	1.6900	Ti-6Al-4V
2	0.71775	0.71532	0.82629	0.82687	1.5730	1.5725	1.6890	Ti-6Al-4V
3	0.71743	0.71566	0.82311	0.82332	1.5700	1.5715	1.6890	Ti-6Al-4V
4	0.71764	0.71546	0.82649	0.82677	1.5730	1.5730	1.6895	Ti-6Al-4V
5	0.71616	0.71731	0.82677	0.82779	1.5740	1.5750	1.6890	Ti-6Al-4V
6	0.71789	0.71442	0.82350	0.82361	1.5710	1.5695	1.6895	Ti-6Al-4V
7	0.71639	0.71787	0.82588	0.82701	1.5720	1.5730	1.6890	Ti-6Al-4V
8	0.71789	0.71590	0.82631	0.82696	1.5720	1.5725	1.6890	Ti-6Al-4V
9	0.71708	0.71639	0.82585	0.82624	1.5720	1.5720	1.6870	Co-Cr
10	0.71763	0.71792	0.82627	0.82669	1.5730	1.5735	1.6890	Co-Cr
11	0.71791	0.71686	0.82613	0.82591	1.5730	1.5765	1.6870	Co-Cr
12	0.7163	0.71701	0.82508	0.82619	1.5750	1.5730	1.6880	Co-Cr
13	0.71714	0.69682	0.82681	0.82805	1.5750	1.5760	1.6880	Co-Cr
14	0.7159	0.71719	0.82617	0.82785	1.5730	1.5740	1.6870	Co-Cr
15	0.71638	0.71824	0.82548	0.82641	1.5720	1.5725	1.6885	Co-Cr
16	0.71708	0.71752	0.82550	0.82605	1.5750	1.5760	1.6890	Co-Cr
17	0.71765	0.71917	0.82868	0.82963	1.5750	1.5750		
18	0.71688	0.71789	0.82553	0.83822	1.5750	1.5755		
19	0.71807	0.71841	0.82865	0.82875	1.5730	1.5750		
20	0.71748	0.71839	0.82678	0.82733	1.5720	1.5730		

Specimen #	Difference		Difference		Difference
1	-0.0019		-0.0002		-0.0005
2	0.0024		-0.0006		0.0005
3	0.0018		-0.0002		-0.0015
4	0.0022		-0.0003		0.0000
5	-0.0011		-0.0010		-0.0010
6	0.0035		-0.0001		0.0015
7	-0.0015		-0.0011		-0.0010
8	0.0020		-0.0007		-0.0005
9	0.0007		-0.0004		0.0000
10	-0.0003		-0.0004		-0.0005
11	0.0011		0.0002		-0.0035
12	-0.0007		-0.0011		0.0020
13	0.0203		-0.0012		-0.0010
14	-0.0013		-0.0017		-0.0010
15	-0.0019		-0.0009		-0.0005
16	-0.0004		-0.0005		-0.0010
17	-0.0015		-0.0010		0.0000
18	-0.0010		-0.0127		-0.0005
19	-0.0003		-0.0001		-0.0020
20	-0.0009		-0.0006		-0.0010

NOT Put in Liquid Nitrogen